

# Online Worksheet

## What it can do for your company

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Globalization has changed the business environment for many analytical laboratories. Competition has increased dramatically, forcing laboratories to reduce costs without jeopardizing quality and service. New government regulations have forced laboratories to implement additional security and accountability measures, further increasing the cost of doing business. These changes have driven independent laboratories to increase their size and to diversify their production through mergers, joint ventures and buy-outs.

These companies are facing many challenges. They may have laboratories in several countries, the laboratories may range in size, and they may cover a broader spectrum of industries. Some member laboratories or branches may need to meet strict regulatory requirements while others may not.

To compete effectively in the global market, companies need to find ways to standardize their production while retaining independent and dynamic branches. This independence is vital to maintain quick responses to local requests, and to continue providing the same service to established customers. In addition, they have to examine the work processes in each laboratory and find ways to reduce inefficiencies so that they can increase their ability to satisfy their customers while remaining competitive and meeting regulatory requirements.

### The LIMS challenge

One of the biggest challenges facing these newly formed companies is dealing with *Laboratory Information Management Systems (LIMS)*. Each member laboratory probably has its own LIMS to manage information and ensure data quality. However, the functionalities of each LIMS are likely different and data management and data quality may not meet corporate standards. There is a need to standardize laboratory production and simplify the LIMS structure to maximize efficiency and productivity of the whole company.

Several approaches are possible to simplify the LIMS structure within a diversified company. One approach might be to implement a corporate LIMS. However, this approach may not be feasible for the following reasons:

- Member laboratories already have a LIMS running with local technical and user support .
- Member laboratories have a LIMS that is integrated with their local laboratory accounting system.
- All client interfaces are set up and very hard to change (e.g. invoicing, certificates of analysis, data exporting formats, internet interfaces).
- High training cost.
- Barriers to acceptance of new LIMS.
- Most LIMS are specific to one type of laboratory and are not easily used with another.
- Long implementation time (approximately 2 years) can be disruptive to the functioning of the whole laboratory .

Another approach might be to implement an electronic lab notebook at the laboratory bench level without changing the entire LIMS in each laboratory. This would accomplish both objectives: *simplify the LIMS structure and standardize laboratory production and data quality*. The corporation can then be satisfied that all laboratory procedures are being done according to corporate standards without having to incur the cost and inconvenience of changing an entire LIMS system in each laboratory. The advantages of this approach are:

- Member laboratories can keep their existing LIMS.
- No changes to existing accounting and client interfaces.
- Lower training costs because fewer people need to be trained.
- Higher acceptance because of lower disruption of current practices.
- Shorter implementation time is less disruptive and only affects the production section.

Discussion around standardization and simplification of the LIMS reveal concerns from different groups within the laboratory:

#### *Laboratory Management*

- How can data collection, manipulation, formatting and quality control be standardized without interfering with the business rules of each member laboratory business rules?
- How can a LIMS remain flexible and adaptable to the changing needs of each laboratory?

#### *Quality Control (QC) Management:*

- How can production be standardized?
- How can common Standard Operating Procedures (SOPs) be shared among laboratories that perform the same technique?
- How can a standard QA/QC methodology be implemented in each laboratory and monitored by a central office?

#### *Information Systems (IS) Group:*

- How can the LIMS data structure be simplified?
- How can the need for IS staff be minimized for routine tasks or small changes to the LIMS in each laboratory?

#### *Supervisors:*

- How can techniques be programmed without IS help?
- How can routine tasks (linking instruments, adding formulas, formatting results) be accomplished without IS help?

#### *Technicians:*

- How to create or modify worksheet templates for common tasks without the help of IS staff?
- How can time be better used by reducing the need to perform repetitive tasks?
- How can data handling errors be minimized?

#### *Clients:*

- How can the client be sure that the laboratory is using good laboratory practices and following approved quality assurance and quality control methods?

## Using Online Worksheet to simplify the LIMS and standardize laboratory production

Companies with more than one laboratory and several branches often have very complex LIMS because the LIMS structure is often different in each laboratory or branch. However, a close look at the LIMS system reveals a common pattern at the lab bench level, reflecting the production of the laboratory (Figure 1).

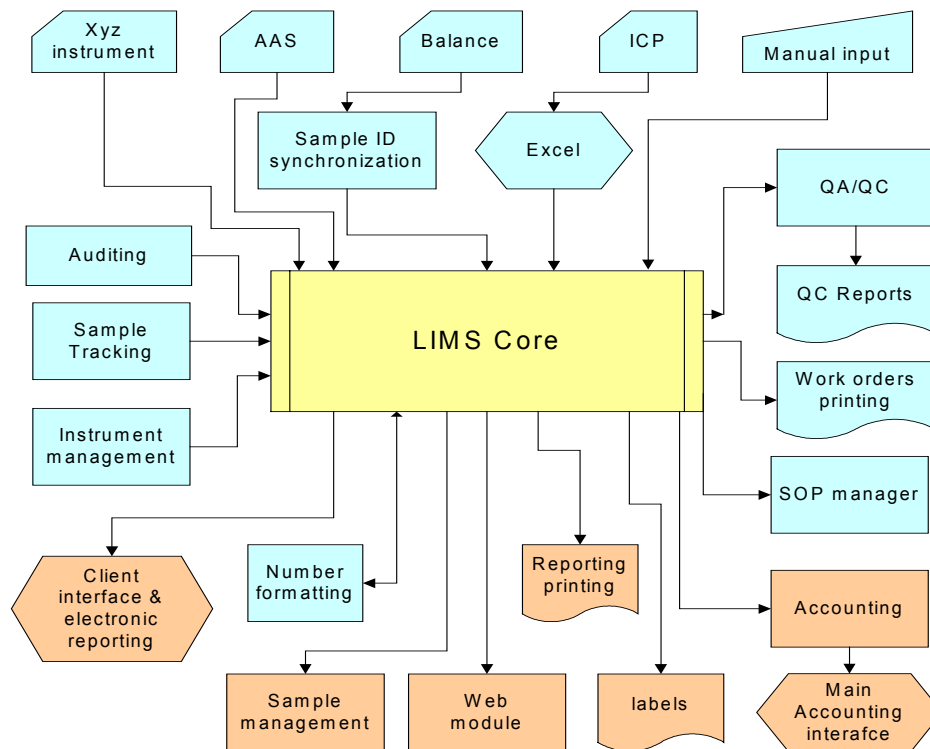


Figure 1. Typical LIMS structure

At the lab bench level, every laboratory performs certain tasks (often using a LIMS), independent of the country it is located in or the product or service it provides:

- Register work requests & schedule work
- Print analytical worksheets
- Monitor and communicate sample/technique backlogs
- Acquire and store analytical data
- Monitor the quality for all analytical work
- Approve analytical data for client release
- Protect security of all data
- Track and locate samples in storage

All what is needed to simplify the LIMS structure is to separate business level information (LIMS) from the laboratory production level information (Online Worksheet) (Figure 2). Standardization then becomes easy to implement. The laboratory production is standardized regardless of the country where the laboratory is located or the type of laboratory (environmental, metal, food, etc).

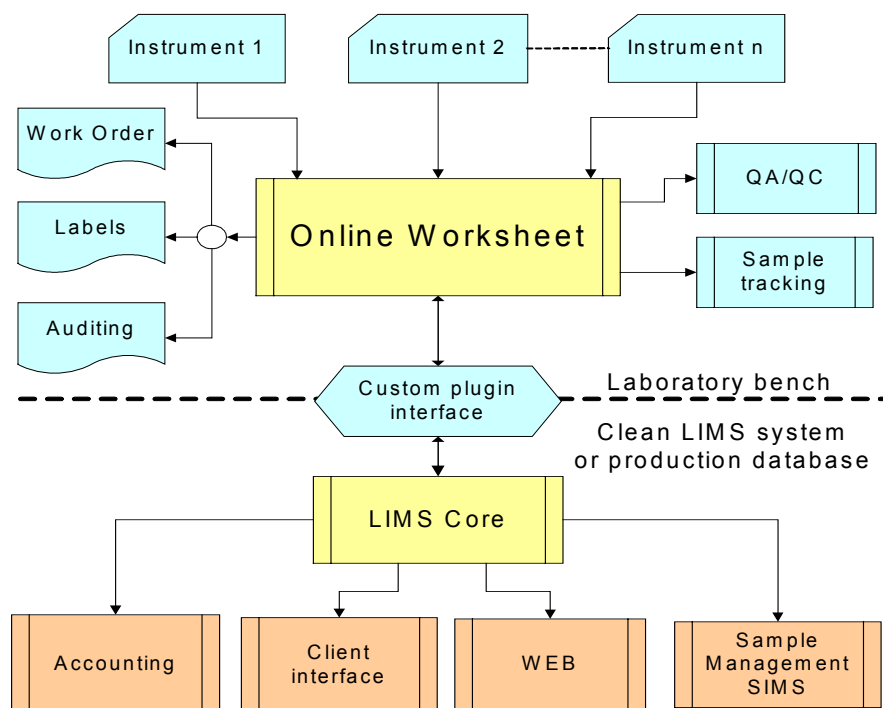


Figure 2. Online Worksheet & LIMS

Although the simplification of the LIMS and the standardization of the laboratory production are the primary objectives, the new system must make the jobs of the bench personnel easier to be successful.

### How Online Worksheet meets the laboratory needs

As illustrated above, Online Worksheet can be used to simplify the LIMS structure and standardize production. Standardization, in this case, means to have a common system shared by all laboratories that:

- Manages all techniques
- Handles all instrument interfacing
- Standardizes all number formatting
- Integrates with a powerful QA/QC system
- Centralizes auditing by technique
- Is well accepted and easily used by all staff
- Is compliant with regulations for electronic records (e.g. 21 CFR Part 11)

### Online Worksheet – Technique oriented files

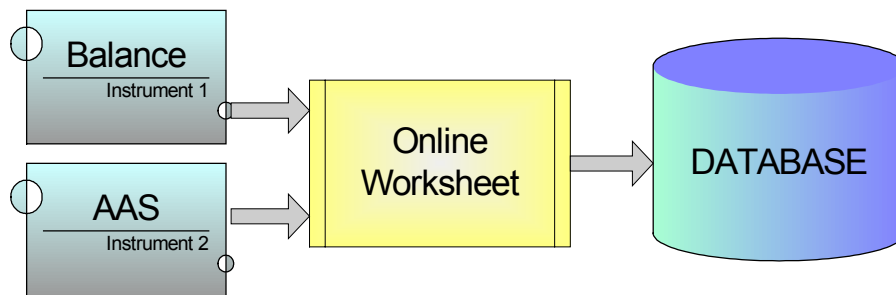
Online Worksheet is a spreadsheet for the chemist that has formulas and features very similar to Excel (thus shortening the learning time). The worksheet has a file browser that groups all files by technique. Any worksheet file can be stored as a template and whenever it is needed, a new worksheet can be generated based on this template. The template holds all the technique-related information (e.g. formulas, units, required analysis, QC samples).

Sample ID	*A aas@T/Hg mg/L mjensen	*B aas@Diss/Hg mg/L mjensen	*D Reading ug/L mjensen	*E Aliquot mL mjensen	*F Volume mL mjensen	*G diln Aliquot mL	*H diln Volume mL	*I @Diss/Hg mg/l mjensen
1 QT28-Hg	1.57		1.573	1	50	2.5	50	
2 QT28-Hg	1.54		1.544	1	50	2.5	50	
3 EW23 020417 0000	< 0.0001	< 0.0001	0.038	25	31	1	1	
4 EW23 DISSOLVED			0.016	25	31	1	1	< 0.0001
5 EW27 020417 0000	0.0003		0.233	25	31	1	1	
6 EW29 020417 0000	0.0001		0.089	25	31	1	1	
7 EW86 020417 0000	< 0.0001		0.054	25	31	1	1	
8 EW87 020417 0000	0.0017	0.0015	1.381	25	31	1	1	
9 EW87 DISSOLVED			1.179	25	31	1	1	0.0015
10 EW90 020417 0000	0.0001		0.101	25	31	1	1	
11 EW91 020417 0000	0.046		3.696	25	31	5	50	
12 EW95 020417 0000	0.013	0.0063	1.029	25	31	5	50	
13 EW95 DISSOLVED			5.077	25	31	1	1	0.0063
14 EW37 020417 0000	0.0063	0.0001	2.035	10	31	1	1	
15 EW37 DISSOLVED			0.090	25	31	1	1	0.0001
16								
17								

Techniques are managed through the worksheet templates and can be shared via the web.

**Wide range of instrument interfaces and client parser available:**

Any instrument that generates an output can be linked to the worksheet. Because each technique can use many instruments to generate the final result, many instruments can be linked to the same worksheet. All instrument records (i.e. Calibration data) are stored with the worksheet for traceability.



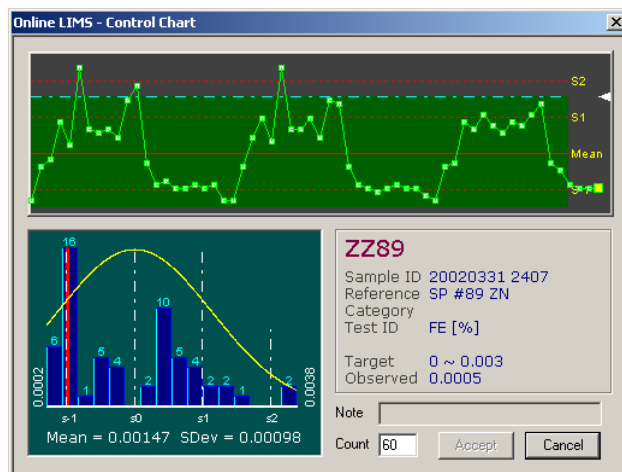
**Advanced number formatting system**

Analytical data is the product of a laboratory. Online Worksheet includes advanced formulas similar to those in Excel (AVG, IF, STATISTICAL, etc). The final number is formatted with a sophisticated number formatting system, that even rounds to the nearest even value:

- Decimal rounding to the nearest even value (conventional rounding leads to bias error)
- Significant figures rounding
- Rounding by any range defined by the chemist.

### ***Integrated with a powerful QA/QC system.***

Online Worksheet is integrated with a professional QC module that acts as an interactive tool to the chemist. If any observed value is out of specification, a window will automatically pop up before the chemist releases data. The QC system includes a reference material database where each test can be charted instantly in many different formats. It supports the extensive REPLICATE statistic. Online's QC is unique and has received highly favourable reviews by client QC officers.



### ***Centralize auditing by technique.***

Auditing is a feature that can be as simple as an ID and time stamp on a log file. But routine work and checking is slowed down when auditing is made complex through database queries. Auditing is not only a legal requirement; it is a tool to check on the current work, before it is completed. Online Worksheet centralizes all auditing by the worksheet and the current job. So a senior chemist can check current work in real time.

### ***Online Worksheet training and acceptance***

The acceptance of Online Worksheet by laboratory staff is considerably enhanced by their participation in the design and programming of the worksheet templates (techniques). This participation is the key philosophy of Online Worksheet. Chemists are more likely to use the tool because they develop their own templates and customize them based on their needs. They have the ability to make changes as required, without having to depend on the information technology staff of the company. Information technology staff of the company can then concentrate on customizing the LIMS for accounting, statistics, reports, etc. The overall use of human resources for the use and maintenance of the LIMS is more directed and efficient.

### ***How Online Worksheet meets 21 CFR Part 11***

The 21 CFR Part 11 was created by Food and Drugs Administration in the US and requires computerized systems, their electronic records, and their electronic signatures to meet certain legal requirements. Online Worksheet is compliant through:

- *Unique identification of all users in the system:* Each user needs his/her own user name and password to log in.

- *Automatic audit trail created for all entries and changes to data in the system:* Each cell in the Worksheet is linked to an attribute that will display its source, whether it comes from the instrument or whether it was typed in. Recognition of changes are viewed by colour and font attributes. More information regarding on the traceability of each cell is retrieved by a simple right mouse click. Additional auditing is stored on each worksheet header and each column header (who locked the column, who approved the results, etc.)
- *Audit trail includes date, time and ID:* all included
- *Old versions of data are never overwritten, but given an "old" status* If full Auditing is selected, all older data is stored on a log file with time and ID stamp. Even full auditing can be started after data is released (to avoid redundancy auditing when the technician is working and calibrating). Auditing even includes all instrument output, stored together with the worksheet.
- *Large number of topics to be included in SOPs:* Each technique can be stored as an HTML and called as a help file. Can include pictures, charts, links to other Web sites, etc.
- *Proof that the SOPs are used accordingly:* Online Worksheet stores all instrument data/output records, including calibration and reslopes within the worksheet file, allowing the QC and auditors to verify that the SOP's were properly followed.

## Cost Analysis

A cost analysis can be done by looking at cost reductions associated with using Online Worksheet. By using Online Worksheet, laboratory instruments can be directly integrated into a database, which can produce significant time savings for most analytical laboratories. Instrument integration includes anything from a simple instrument connection (that reduces data typing) to complex data processing and the reporting of final results to the LIMS.

For example, the following table estimates the costs related to manual data handling for a standard laboratory with 13 instruments. Online Worksheet can save this laboratory \$435.00 per shift per day by replacing manual data handling alone. When the time and cost savings associated with automated data processing, quality control, and reporting are included, the cost savings can be as much as \$ 570.00 per day. At that rate, Online Worksheet can pay for itself within 3 months.

QTY	INSTRUMENT	HR Rate	Hours per day	Wages per shift
2	ICP, XRF	18.00	3.5	126.00
4	AAS	15.00	2.5	150.00
5	Balance	12.00	2	120.00
1	Titrator	15.00	1	15.00
1	Leco	12.00	2	24.00
Total for one shift based on 13 instruments				<b>\$ 435.00</b>

## **Key Benefits**

The benefits of using Online Worksheet to simplify the LIMS and standardize laboratory production can be described at several levels:

### *Lab Management*

- Standardizes the data collection, manipulation, formatting and quality control at the bench level without interfering with the laboratory business rules
- Allows high flexibility and continuous adaptation to the changing needs of each laboratory

### *Quality Control (QC) Management:*

- Standardizes the production. For example, common Standard Operating Procedures (SOPs) are shared among laboratories that perform the same technique, thus standardizing the technique no matter where the laboratory is located.
- Comes integrated with a advanced QA/QC module that can be used to monitor quality control from a central office (remotely via Internet).

### *Information Systems (IS) Group:*

- User-friendly worksheets and automated data management can reduce dependence on IS staff for routine tasks

### *Supervisors:*

- Software helps supervisors track and manage work flow in the laboratory

### *Technicians:*

- Technicians can use software to create or modify worksheet templates for common tasks without the help of IS staff
- Reduces the need for technicians to perform repetitive tasks (e.g. data entry) and reduces the risk of data handling errors

### *Clients:*

- Provides documentation to demonstrate that the laboratory is using good laboratory practices, following approved quality assurance and quality control methods, and that all procedures can be traced.

## ***Productivity benefits***

Online-Worksheet brings more productivity benefits to the laboratory than any other system of its type. The most obvious gain in productivity is through the elimination of manual data entry because of the wide selection of instrument interfacing included in the worksheet. There is also the associated decrease in data entry errors. Analytical work can be better scheduled therefore minimizing “downtime” and maximizing batch size. Quality control checks are more visible and centralized data can be shared by several departments. Laboratory methods and work practices can be improved continuously because Online Worksheet provides the laboratory with the ability to monitor, track and communicate data and quality control information.

## Conclusion

The companies that have more than one laboratory and several branches often have very complex LIMS because each member laboratory has their own LIMS to manage information and ensure data quality. However, the functionalities of each LIMS are likely different and the data management and data quality may not meet the corporate standards. Online Worksheet can be used to standardize laboratory production and simplify the LIMS structure to maximize the productivity and competitiveness of the whole company without incurring the cost of replacing the whole LIMS.

*Online Worksheet* does this by separating the information at business level (LIMS) from the laboratory production or bench level (Online Worksheet). It can be seamlessly integrated with any existing LIMS and becomes a common system shared by all laboratories that:

- Manages all techniques and handles all instrument interfacing
- Standardizes all number formatting
- Integrates with a powerful QA/QC system
- Centralizes auditing by technique
- Is well accepted and easily used by the lab staff.
- Helps you achieve '21 CFR Part 11' compliance.

## References

Cain, T. 1997. LIMS as a means, not an end. *International Laboratory*:13-17.  
Oelker, G. 2002. How does LIMS use help laboratory function.  
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